

## Nuclear Regulatory Commission

## § 26.111

split under the provisions of this subpart, the predetermined quantity must include an additional 15 mL.

(b) If the quantity of urine in the first specimen provided by the donor is less than 30 mL, the collector shall take the following steps:

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen containing at least 30 mL. The collector shall provide the donor with a separate collection container for each successive specimen;

(2) Once the donor provides a specimen of at least 30 mL, the collection must end. If the specimen quantity is at least 30 mL but is less than the licensee's or other entity's predetermined quantity, the licensee or other entity may not require the donor to provide additional specimens and may not impose any sanctions on the donor. If the donor provides a specimen of 30 mL or more, but the specimen quantity is less than the predetermined quantity, the collector shall forward the specimen to the HHS-certified laboratory for testing. If the donor provides a specimen of at least the predetermined quantity, the specimen may be processed under the FFD program's usual testing procedures;

(3) If the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt to provide a specimen of the predetermined quantity, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the "shy bladder" procedures in § 26.119; and

(4) Neither the donor nor the collector may combine specimens. The collector shall discard specimens of less than 30 mL, except if there is reason to believe that the donor has diluted, adulterated, substituted, or otherwise tampered with the specimen, based on the collector's observations of the donor's behavior during the collection process or the specimen's characteristics, as specified in § 26.111. If the collector has a reason to believe that a specimen that is 15 mL or more, but less than 30 mL, has been diluted, adul-

terated, substituted, or altered, the collector shall prepare the suspect specimen for shipping to the HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

### § 26.111 Checking the acceptability of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered or substituted the specimen.

(b) Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the custody-and-control form.

(c) If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on specimen temperature or other observations made during the collection, the collector shall contact the designated FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process or whether other circumstances may explain the observations. The FFD program manager or MRO may require the donor to provide a second specimen as soon as possible under direct observation. In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered or substituted the specimen.

## § 26.113

(d) Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility.

(e) As much of the suspect specimen as possible must be preserved.

(f) An acceptable specimen is free of any apparent contaminants, meets the required basic quantity of at least 30 mL, and is within the acceptable temperature range.

### § 26.113 Splitting the urine specimen.

(a) Licensees and other entities may, but are not required to, use split-specimen methods of collection.

(b) If the urine specimen is to be split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the collector shall take the following steps:

(1) The collector shall instruct the donor to urinate into a specimen container;

(2) The collector, in the presence of the donor and after determining specimen temperature as described in § 26.111(a), shall split the urine specimen. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B. If the quantity of urine available for Bottle B is less than 15 mL, the collector shall pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity testing; and

(3) The collector shall ask the donor to observe the splitting of the urine specimen and to maintain visual contact with both specimen bottles until the custody-and-control form(s) for both specimens are completed, the specimens are sealed, and the specimens and form(s) are prepared for secure storage or shipping.

(c) Licensees and other entities may use aliquots of the specimen collected for validity screening and initial validity and drug testing at the licensee testing facility, as permitted under § 26.31(d)(3)(ii), or to test for additional

## 10 CFR Ch. I (1–13 Edition)

drugs, as permitted under § 26.31(d)(1)(i)(A), but only if sufficient urine is available for this testing after the specimen has been split into Bottle A and Bottle B.

### § 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

(1) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result;

(2) The donor has presented, at this collection, a urine specimen that falls outside the required temperature range;

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen; and

(4) A directly observed collection is required under § 26.69.

(b) Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable.

(c) The collector shall explain to the donor the reason for direct observation of the collection under paragraph (a) of this section.

(d) The collector shall complete a new custody-and-control form for the specimen that is obtained from the directly observed collection. The collector shall record that the collection was observed and the reason(s) for the directly observed collection on the form.

(e) The collector shall ensure that the observer is the same gender as the